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Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

The attached application for patent term extension of U.S. Patent No. 6,068,832 was filed on August 19, 2010, under 35 U.S.C. § 156. Please note that a patent term extension application for U.S. Patent No. 7,067,502 for NDA 22-518 for the human drug product DULERA® (mometasone furoate and formoterol fumarate) was filed concurrently, pursuant to the provisions of 37 C.F.R. § 1.785.

The assistance of your Office is requested in ascertaining whether the product identified in the present application, DULERA® (mometasone furoate and formoterol fumarate), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its FIRST commercial marketing or use (as required by section 156(a)(5)(A)). Additionally, the assistance of your office is requested to provide the approval date of NDA No. 22-518 such that the United States Patent and Trademark Office can determine whether the application for patent term extension was filed within the sixty-day period of 35 U.S.C. § 156(d)(1). Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our preliminary analysis of the application to date indicates that the subject patent would NOT be eligible for extension of the patent term under 35 U.S.C. § 156 unless the Food and Drug Administration considers the combination of mometasone furoate and formoterol fumarate in DULERA® to be a single entity. According to the statute:

> (a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent, which shall include any patent term adjustment granted under section 154(b) if —
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> . . .
>
> (5)(A) except as provided in subparagraph (B) or (C), the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred;
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> . . . .
>
> (f) For purposes of this section:
>
> (1) The term "product" means:

(A) A drug product.

. . .

(2) The term "drug product" means the active ingredient of—

(A) a new drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act)

. . .

including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.

35 U.S.C. § 156.

It is noted that the electronic Orange Book accessed December 30, 2010, indicates the active ingredients of the drug product which was the subject of New Drug Application (NDA) No. 22-518 as mometasone furoate and formoterol fumarate (see exhibit 1-attached hereto). The term "product" as used in 35 U.S.C. § 156 includes any new drug or antibiotic drug, as a single entity or in combination with another active ingredient. See 35 U.S.C. § 156(f). "For a product which contains a plurality of active ingredients . . . the statute must be analyzed with respect to each active ingredient." See "Request for Patent Term Extension Final Decision," dated March 3, 1994, in U.S. Patent No. 4,529,601 (exhibit 2-attached hereto). If a drug product contains two active ingredients and both of the active ingredients have been previously approved, then regulatory review of the combination product cannot be relied upon for extension of a patent claiming the approved drug product. See In re Alcon Laboratories, 13 USPQ2d 1115 (Comm'r 1989). Since mometasone furoate and formoterol fumarate have been previously approved individually, their use in a combination product does not appear to comply with 35 U.S.C. § 156(a)(5)(A), *i.e.*, the approval of DULERA®, the aerosol containing mometasone furoate and formoterol fumarate of NDA No. 22-518, would not appear to constitute the first permitted commercial marketing or use of the product as required by 35 U.S.C. § 156(a)(5)(A). Specifically, mometasone furoate has been previously approved for use in Elocon® in 1987 (see exhibit 3-attached hereto). Similarly, formoterol fumarate has been previously approved for use on February 16, 2001 (see exhibit 4-attached hereto) as Foradil®. Thus, the combination product does not appear to constitute the first permitted commercial marketing or use of either active ingredient of the product. Thus, U.S. Patent No. 6,068,832 does not appear to be eligible for patent term extension based upon the regulatory review of DULERA® the aerosol contianing mometasone furoate and formoterol fumarate which was the subject of NDA No. 22-518. See also Fisons plc v Quigg, 8 USPQ2d 1491 (D.D.C. 1988).

In an effort to establish eligibility, Applicant asserts that since the product is a synergistic combination of mometasone furoate and formoterol fumarate, it should be considered a single active ingredient for patent term extension purposes, and therefore be eligible for patent term extension under 35 U.S.C. § 156. To that end, Applicant has submitted Exhibits 3, 4 and 5 to their PTE application which are alleged to show the synergistic effects of the conbined product which Applicant concludes makes it a different active ingredient than either mometasone furoate

alone or formoterol fumarate alone.

It is the position of the USPTO that a product which is nothing more than a combination of previously approved active ingredients fails to satisfy 35 U.S.C. § 156(a)(5)(A). Whether the product is a synergistic or nonsynergistic combination of active ingredients is of no consequence to a determination of compliance with 35 U.S.C. § 156(a)(5)(A). Although not at issue in the application for patent term extension for U.S. Patent No. 4,587,252 which spawned Arnold Partnership v Dudas, 70 USPQ2d 1311 (Fed. Cir. 2004), the court there provided their views on whether a patent directed to a synergistic combination of drugs patents would qualify for a patent term extension under § 156. Specifically, the court stated, "[m]oreover, this court doubts that synergistic effects are an appropriate distinction for term extension policies, particularly where the statutory language does not distinguish at all between synergistic and non-synergistic combinations."

Therefore, the approval of DULERA® (mometasone furoate and formoterol fumarate) referenced in the application for patent term extension of U.S. Patent No. 6,068,832 does not appear to represent approval as "the first permitted commercial marketing or use of the product" as required by § 156(a)(5)(A), and U.S. Patent No. 6,068,832 is **ineligible** for extension.

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

Mary C. Till
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Barry Jacobson, Esq.
Merck
2000 Galloping Hill Rd.
Kenilworth, NJ 07033